



#### EA MLA Signatory Český institut pro akreditaci, o.p.s. (Czech Accreditation Institute) Hájkova 2747/22, Žižkov, 130 00 Praha 3

issues

according to section 16 of Act No. 22/1997 Coll., on technical requirements for products and on changes and amendments to some Acts, as amended

# CERTIFICATE OF ACCREDITATION

No. 498/2025

IVF Czech Republic s.r.o. with registered office U Lomu 638, 760 01 Zlín Company Registration No. 25594575

for the Medical Laboratory No. **8122**Laboratories of the Clinic of Reproductive Medicine and Gynaecology

#### Scope of accreditation:

Examinations in the field of laboratory andrology for IVF and clinical biochemistry including shared examinations to the extent as specified in the appendix to this Certificate.

This Certificate of Accreditation is a proof of accreditation issued on the basis of assessment of fulfillment of the accreditation criteria in accordance with

### ČSN EN ISO 15189 ed. 3:2023

In its activities performed within the scope and for the period of validity of this Certificate, the abovementioned Accredited Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the Accredited Body meets the specified accreditation requirements in accordance with the relevant regulations applicable to the activity of an accredited conformity assessment body.

This Certificate of Accreditation replaces, to the full extent, Certificate No.: 158/2024 of 08/04/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: 08/04/2029

Prague: 02/10/2025





Signed in the Czech original: Marek Vyskočil on 02/10/2025

Milena Lochmanová Director of the Department of Medical Laboratories Czech Accreditation Institute

This translation of the Czech original has been issued by: Jana Chvalovská

# The Appendix is an integral part of Certificate of Accreditation No. 498/2025 of 02/10/2025

# Accredited entity according to ČSN EN ISO 15189 ed. 3:2023:

## IVF Czech Republic s.r.o.

CAB Number 8122, Laboratories of the Clinic of Reproductive Medicine and Gynaecology U Lomu 638, 76001 Zlín

## **Medical laboratory locations:**

IVF Laboratory
U Lomu 638, 760 01 Zlín
Biochemical Laboratory
U Lomu 638, 760 01 Zlín

## 1. **IVF Laboratory**

#### **Examinations:**

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom <sup>1</sup>				
Laboratory examinations for IVF									
1.	Semen evaluation	Macroscopy; Microscopy	SOP_mL_01_r11	Semen	-				

#### 2. Biochemical Laboratory

#### **Examinations:**

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom <sup>1</sup>			
815 - Nuclear Medicine Laboratory								
1.	Estradiol	Immunoassay with fluorimetric detection	SOP_bL_19_r07; AIA 900	Serum	-			
2.	Follicle-stimulating hormone (FSH)	Immunoassay with fluorimetric detection	SOP_bL_20_r07; AIA 900	Serum	-			
3.	Free Thyroxine (FT4)	Immunoassay with fluorimetric detection	SOP_bL_21_r07; AIA 900	Serum	-			
4.	Human chorionic gonadotropin (HCG)	Immunoassay with fluorimetric detection	SOP_bL_22_r08; AIA 900	Serum	-			
5.	Luteinizing hormone (LH)	Immunoassay with fluorimetric detection	SOP_bL_23_r07; AIA 900	Serum	-			

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom <sup>1</sup>
6.	Progesterone	Immunoassay with fluorimetric detection	SOP_bL_24_r07; AIA 900	Serum	-
7.	Prolactin	Immunoassay with fluorimetric detection	SOP_bL_25_r07; AIA 900	Serum	-
8.	Testosterone	Immunoassay with fluorimetric detection	SOP_bL_26_r07; AIA 900	Serum	-
9.	Thyrotropin (TSH)	Immunoassay with fluorimetric detection	SOP_bL_27_r07; AIA 900	Serum	-
10.	Total Triiodothyronine (TT3)	Immunoassay with fluorimetric detection	SOP_bL_28_r07; AIA 900	Serum	-
11.	Anti-thyroid peroxidase antibodies (Anti-TPO)	Immunoassay with fluorimetric detection	SOP_bL_29_r07; AIA 900	Serum	-

### **Explanatory notes:**

<sup>&</sup>lt;sup>1</sup> The laboratory does not apply a flexible approach to the scope of accreditation

<sup>&</sup>quot;This document is an appendix to the certificate of accreditation. In case of any discrepancies between the English and Czech versions, the Czech version shall prevail, both for the certificate appendix and the certificate itself."